K123082
Page 1 of 5

(the following information is in conformance with 21 CFR 807.92)

MAY 16 2013

Submitter

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Date Summary Prepared: April 24, 2013

Device name

Trade Name: MobileCT Viewer
Common Name: Medical Imaging Software
Classification Name: System, Image Processing, Radiological (21 CFR Part 892.2050, Product Code: LLZ)

Predicate device

K103785 MobileMIM MIM Software Inc.

Indications for Use

The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals.

MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device description

The MobileCT Viewer is a software-based Picture Archiving and Communication System (PACS) used with computing servers and specific mobile devices. DICOM-compliant medical images from CT, MRI, X-ray modalities are stored on the server component. MobileCT Viewer retrieves patent image data securely via a network connection with the server. DICOM files are losslessly compressed for network transfer and downloaded by MobileCT Viewer for display on the mobile device component. Communication and display on the mobile device assist trained professionals in the diagnostic interpretation, review and analysis of the medical images.

MobileCT Viewer includes the capability to perform to the displayed image:

- adjust window width and level (i.e. contrast) values,
- apply view transforms (e.g. zoom, pan, and rotation),
- measure distances, and
- display measurement lines and annotations.

MobileCT Viewer operates on off-the-shelf portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability,

network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

Substantial equivalence

Table 1 provides evidence to facilitate the substantial equivalence determination between MobileCT Viewer and our chosen predicate, Mobile MIM (K103785).

There is a direct correlation between the Indication Statement / Intended Use of MobileCT Viewer with Mobile MIM. Both devices are software applications used by medical professionals in the diagnosis of patients by means of medical images.

MobileCT Viewer and MobileMIM run on the same software platform– Apple iOS, and hardware platform– the Apple iPad (4th generation, late 2012) . MobileCT Viewer's technological characteristics are more limited than that of MobileMIM, as MobileCT Viewer provides only viewing and simple image manipulation (which do not alter the image data, such as window and level, pan and zoom, and image annotation) capabilities. MobileCT Viewer does not provide image processing functions which are intended to alter the image data (e.g. filtering, multiplanar reconstruction, and 3D reconstruction).

MobileCT Viewer's capabilities include support for viewing medical images from modalities not indicated in Mobile MIMs submission: X-ray. This difference does not alter the intended effect of the device (that is, the display of medical images) and does not raise any different types of safety and effectiveness questions. Information including performance data is provided in this submission to assess device performance in viewing images from these added modalities.

In addition, MobileCT Viewer does not support the following advanced image manipulations: image fusion, multiplanar reconstruction (MPR), maximum intensity projection (MIP), or standard update values (SUV). Consistently, the Indications for Use Statement for MobileCT Viewer excludes the advanced image manipulations.

TABLE 1: Device Comparison table between new device and predicate

Item	MobileCT	MobileMIM
Intended Use / Indication for Use	The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals. MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT and MRI. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Receive, Store, Retrieve, Display and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	No	Yes
3D reconstruction, e.g. Multi-Planar Reconstruction (MPR), Maximum Intensity Projection (MIP)	No	Yes
Standard Uptake Value (SUV)	No	Yes
Distance Measurements	Yes	Yes
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	CT, MRI, X-ray	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	Yes
Operating Platform	Yes	Yes
Hardware Requirements	the Apple iPad (4th generation, late 2012)	Apple iOS handheld devices

For a complete discussion of how hazards related to the use of MobileCT Viewer as a diagnostic, review, and analysis tool by trained professionals should be addressed during device development as part of the risk management process, see the Device Use Safety discussion in Part XVI (Software) Chapter 3 (Hazard analysis) of this 510(k) premarket notification. Additionally, a summary of the results of the testing (section 9.6 and section 9.7) done during the Alpha and Beta development stages demonstrate that the device, when used according to operating instructions, can be used safely and effectively.

Summary of testing

Nephosity, Inc. has performed multiple studies with qualified medical professionals. These medical professional tested MobileCT Viewer by evaluating the image quality of the medical images of the supported modalities (i.e. CT, MRI, X-ray) under different environmental conditions. Results of these studies affirm the diagnostic viewing capabilities of MobileCT Viewer when used as indicated.

Additionally, Nephosity, Inc. has conducted performance and functional testing on the MobileCT Viewer software. In all cases, the software passed its performance requirements and met specifications. A summary of the results of the testing (section 9.6 and section 9.7) of Part XVI.

No animal or clinical testing was performed.

Conclusion

Based on a comparison between the MobileCT Viewer and the Mobile MIM and on the performance data provided in this premarket notification submission, it is our belief that the new device is as safe and effective as the predicate device, and does not raise different questions of safety and effectiveness than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Nephosity, Inc.
% Mr. Michael Pan
CEO
615 Grant Avenue, 3F
SAN FRANCISCO CA 94108

Re: K123082
Trade/Device Name: MobileCT Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II .
Product Code: LLZ
Dated: March 30, 2013
Received: April 3, 2013

Dear Mr. Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

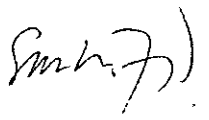
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123082

Device Name: MobileCT Viewer

Indications for Use:

The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals.

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This device is not to be used for mammography.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123082